

RESULTS OF INVESTIGATION: Qualitative tests showed that the article contained borates, benzocaine, camphor, and menthol.

The label consisted of printed and graphic matter in a heavy, blue paint-like substance applied to the plastic material of the container. The printed matter was absent in part, causing the name of the article and place of business of the manufacturer to be unreadable. The quantity of contents statement was inconspicuous due to being printed in extremely small type. No directions for use were given on the label.

LIBELED: 3-15-62, S. Dist. Fla.

CHARGE: 502(c)—when shipped, the information required by 502(b) (1) and (2) to appear on the label, namely, the place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of contents, was not prominently placed thereon with such conspicuousness (as compared with other words and statements in the labeling) as to render it likely to be read by the ordinary individual under customary conditions of purchase and use; 502(e) (2)—the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; 502(f) (1)—its labeling failed to bear adequate directions for use; and 502(f) (2)—the article contained benzocaine, a local anesthetic, and its label failed to bear a statement warning that the article was not to be used in the eyes; that it was not for prolonged use; and that, if the conditions for which it was used persisted or if rash developed, use of the article should be discontinued and a physician consulted.

DISPOSITION: 4-12-62. Default—destruction.

7024. A-D Caine ointment. (F.D.C. No. 47167. S. No. 26-170 T.)

QUANTITY: 96 ctns., 12 2-oz. tubes each, at East Detroit, Mich.

SHIPPED: 8-30-61, from Cedar Rapids, Iowa, by Pharmich Laboratories.

LABEL IN PART: (Tube) "Phar-Med * * * Lanolized A-D Caine Ointment With Tyrothricin Contains natural Vitamins A and D with Tyrothricin (antibiotic) and 3% Benzocaine (anesthetic) in a special lanolized base, non-greasy. * * * Phar-Med, Inc. Distributors Detroit, Michigan."

LIBELED: 2-27-62, E. Dist. Mich.

CHARGE: 502(a)—when shipped, the label contained false and misleading representations that the article was adequate and effective for the relief of skin rash (diaper and heat) and skin irritation (windburn, chafing and "detergent hands"), since the article contained a local anesthetic, benzocaine, which, in itself, was capable of producing skin rashes and skin irritation; and 502(f) (2)—the article was labeled as containing the local anesthetic, benzocaine, and the label failed to bear a statement warning against use of the article in the eyes, against prolonged use, and to discontinue use and consult a physician if a skin rash or irritation developed, or the conditions for which the article was used persisted; and, in that it was suggested for use in the relief of hemorrhoids, and the label failed to bear a statement warning that the user should consult a physician in the case of rectal bleeding.

DISPOSITION: 4-16-62. Consent—claimed by Phar-Med, Inc., East Detroit, Mich., and relabeled.